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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,678	09/15/2003	John P. Troup	8493-US	1877

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EXAMINER
HA, JULIE

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
12/15/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/662,678	TROUP ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-14 and 16-28* is/are pending in the application.

4a) Of the above claim(s) *6,12 and 18-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 7-11, 13-14, 16-17 and 23-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment after Non-final rejection filed on August 4, 2008 is acknowledged. Claims 5, 15 and 29 have been cancelled. Claims 1-4, 6-14 and 16-28 are pending in this application. Claims 6, 12, 18-22 remain withdrawn from further consideration as being drawn to nonelected invention and species. Claims 1-4, 7-11, 13-14, 16-17 and 23-28 are examined on the merits in this office action.

Withdrawn Rejection

1. Rejection of claims 3 and 25 under 35 U.S.C. 112, second paragraph, as having insufficient antecedent basis is hereby withdrawn in view of Applicant's amendment to the claims.

2. Rejection of claims 17 and 28 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is hereby withdrawn in view of Applicant's amendment to the claims.

3. Rejection of claims 23-24 under 35 U.S.C. 102(b) as being anticipated by Madsen et al (US Patent No. 4,898,879) is hereby withdrawn in view of Applicant's amendment to the claims.

4. Rejection of claims 3-4, 7, 25 and 27 under 35 U.S.C. 102(e) and (a) as being anticipated by Hageman et al (US Patent No. 6,420,342) is hereby withdrawn in view of Applicant's amendment to the claims.

5. Rejection of claims 3-4, 7-11 and 26 under 35 U.S.C. 102(e) and (a) as being anticipated by Abbruzzese et al (US Patent No. 6,387,883) is hereby withdrawn in view of Applicant's amendment to the claims.

6. However, in view of Applicant's amendments, new obviousness rejections follow below.

Maintained Rejection

35 U.S.C. 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

For the purpose of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. V. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held in accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976);In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 3-4, 7-11, 13-14, 16 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abbruzzese et al (US Patent No. 6,387,883).

10. Abbruzzese et al teach nutritional compositions for the prevention and treatment of cachexia and anorexia, comprising effective amount of omega-3-fatty acids (LNA, DPA, DHA, and so on); branched-chain amino acids valine, leucine, isoleucine or mixtures thereof; and antioxidant system selected from beta-carotene, vitamin C, vitamin E, selenium, or mixtures thereof (see abstract). The reference teaches that the total amount of branched-chain amino acids (BCAA) useful is about 15-50 g/100 g protein, and would contain up to about 8 g BCAAs per 16 g of total protein. The daily delivery of BCAA is about 5-26 g (see column 9, lines 26-29), meeting the limitation of claims 3-4. The reference teaches that leucine in the amount of 9.08 g and methionine in the amount of 2.78 g per 100 g of protein (see column 9, lines 5-25, or Table 4). Since there is about 10 g of leucine to 100 g of protein, there is about 1:10 ratio of leucine to protein, meeting the limitation of claims 3-4, 7 and 26. The reference teaches

that EPA is in the amount of 1.09 g and DHA is in the amount of 0.46 g (see Table 3), meeting the limitation of claims 8-10. Furthermore, the reference teaches the d-alpha-tocopherol (vitamin E, IU) in the amount of 300.00 Qty/Liter (see Table 6) or 10.65 kg (Table 11). The reference further teaches that composition to treat ulcerative colitis include a protein source that can be intact or hydrolyzed proteins of biological value (see column 3, lines 7-9) and teaches 75% whey protein concentrate as one of the ingredients (see Table 7). The difference between the reference and the instant claims are that the reference does not teach tocopherol in an amount of about 50 mg per serving or at least 150 mg per daily dose, amino acids in 15 g to about 55 g in free and/or salt form per daily dose, and 36 g to about 72 g total essential and/or conditionally essential amino acid per serving. The reference further does not teach about 25 % of leucine in free and/or salt form and the composition providing a ratio of total essential amino acids to total amino acids ranging from about 0.60 to about 0.90.

11. However, it would have been obvious to one of ordinary skill in the art to optimize the conditions of Abbruzzese et al to produce a nutritional composition comprising essential and non-essential amino acids and PUFA such as EPA, since the prior art teaches nutritional composition for treating cancer cachexia. There is a reasonable expectation of success, since “it is the normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is optimum combination of percentages”. The MPEP states: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is

evidence indicating such concentration or temperature is critical. *"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."* In re Aller, *220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)* (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("*The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.*"); In re Hoeschele, *406 F.2d 1403, 160 USPQ 809 (CCPA 1969)* (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Therefore, there is a reasonable expectation of success to optimize the concentrations of the tocopherol and essential amino acid concentrations, since it is "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is

the optimum combination of percentages" and one of ordinary skill in the art would experiment with different concentrations to produce the optimal product. From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Response to Applicant's Arguments

12. Applicant argues That "Abbruzzese fails to describe or suggest the claimed compositions that comprise (a) leucine, either free and/or salt form, in the amount of at least about 25%; and (b) a ratio of total essential amino acids, and optionally, conditionally essential amino acids to total amino acids ranging from about 0.60 to about 0.90." Applicant further argues that "one of ordinary skill in the art, would not have the knowledge nor motivation to arrive at the presently-claimed composition."

13. Applicant's arguments have been fully considered but have not been found persuasive. Abbruzzese reference teaches a nutritional composition comprising leucine and other essential amino acids, non-essential amino acids, PUFA such as EPA. There is a reasonable expectation of success, since "it is the normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is optimum combination of percentages". One of ordinary skill in the art would have been motivated to optimize the concentrations of each component for the optimal nutritional composition. All of the

components to the nutritional composition recited in the instant claims are disclosed in the reference. It would have been obvious to one of ordinary skill in the art to optimize the nutritional composition disclosed in the reference to obtain the best nutritional composition. Therefore, there is a reasonable expectation of success to optimize the concentration of the tocopherol and leucine and other essential amino acid concentrations, since it is "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages" and one of ordinary skill in the art would experiment with different concentrations to produce the optimal product. From the teachings of the reference, it is apparent that one of the ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence to the contrary.

14. Claims 1-2 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen et al (US Patent No. 4,898,879).

15. Madsen et al teach nutritional compositions comprising L-leucine (about from 19.4 to 19.8%), L-isoleucine (16.2 to 16.4%), L-valine (14.5% to 14.8%), L-lysine (10.2% to 10.3%), L-methionine (1.1 to 1.2%) and so on (see column 3, lines 10-25). The reference also teaches that the essential amino acids should comprise about from 60 to 75% by weight of the total amino acids in the composition (see column 3, lines 32-34). The difference between the reference and the instant claims is that the reference

does not teach that leucine is present in an amount of at least 25% to about 95% by weight or at least 25% by weight based on the total amino acids, and said composition provides a ratio of total essential amino acids to total amino acids ranging from about 0.60 to about 0.90.

16. However, it would have been obvious to one of ordinary skill in the art to optimize the conditions of Madsen et al to produce a nutritional composition comprising essential and non-essential amino acids, since the prior art teaches nutritional composition for treating different disorders. There is a reasonable expectation of success, since "it is the normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is optimum combination of percentages". The MPEP states: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. *"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."* *In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)* (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("*The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to*

determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969)* (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Therefore, there is a reasonable expectation of success to optimize the concentrations of the tocopherol and essential amino acid concentrations, since it is "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages" and one of ordinary skill in the art would experiment with different concentrations to produce the optimal product. From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Response to Applicant's Arguments

17. Applicant argues that "the amended claims 1-2, 23 and 24 are drawn to compositions that consist essentially of leucine and at least one essential amino acid in

free and/or salt form, wherein leucine in free and/or salt form and total leucine, respectively, are present in an amount of at least about 25% by weight based on the weight of the total amino acids. The level of leucine in Madsen's composition is lower than that of the claimed compositions. Madsen's composition has a ratio of 0.51, the value of which is lower than that of the presently-claimed composition."

18. Applicant's arguments have been fully considered but have not been found persuasive. Madsen teaches nutritional compositions comprising L-leucine (about from 19.4 to 19.8%). Both the reference and the instant claims recite, "about" in regard to the amount of leucine content ("at least about 25% to about 95%" for the instant claims, and "about from 19.4 to 19.8%" from Madsen reference). Furthermore, the reference teaches that the essential amino acids should comprise about from 60 to 75% by weight of the total amino acids in the composition (see column 3, lines 32-34). This is within the limit of the ratio of from about 0.6 to about 0.90. Furthermore, Madsen teaches that the leucine (about 19.4 to 19.8%), isoleucine (16.2 to 16.4%), lysine (10.2 to 10.3%) and methionine (1.1 to 1.2%) which are essential amino acids. It would have been obvious to one of ordinary skill in the art, reading the Madsen reference, optimize the concentration of the essential amino acids. The lower % of these essential amino acids added together comes to 46.9%. One of ordinary skill in the art would have been motivated to optimize the essential amino acid concentration in the nutritional composition to achieve the optimal nutritional composition. Therefore, there is a reasonable expectation of success to optimize the concentrations of the tocopherol and essential amino acid concentrations, since it is "the normal desire of scientists or

artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages" and one of ordinary skill in the art would experiment with different concentrations to produce the optimal product. From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

19. Claims 3-4, 7, 17, 25 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hageman et al (US Patent No. 6,420,342) in view of Salvati et al (US Patent No. 6,953,679).

20. Hageman et al teach a nutritional, pharmaceutical or dietetic preparation can be manufacture in dry form, as bar, as powder, as tablet, and cookie or as cereal (see column 5, lines 60-63). The reference teaches for products for sportsmen the following mixtures of amino acids appeared to be especially beneficial for muscle growth, when consumed in an amount of more than 2 and preferably more than 4 g per daily dose: 3-10 wt% histidine, 5-15% isoleucine, 10-23% % leucine, 10-23% lysine, 5-15% methionine, 5-15 wt % phenylalanine, and 5-15 wt % threonine (see column 6, lines 59-67 and column 7, line 1). Furthermore, the reference teaches that when proteins are included in the nutritional preparations, the amount that is included depends on the application (see column 6, lines 39-41) and the proteins are proteins of dairy, vegetable

or animal origin, such as skimmed milk powder, whey powder, egg white powder, potato protein, soy protein, etc., or hydrolysates, or mixtures thereof (see column 6, lines 27-32). The reference teaches that when proteins are included in the nutritional preparation, the amount that is included depends on the application of the product. In complete formula typically an amount of 5-120 g per daily dose…for young infants the amount will be in the range 5-15 g per daily dose...in complete enteral nutrition for feeding surgery patients, typically 50-120 g per daily dose…In supplement typically 0-60 g protein per daily dose will be included (see column 6, lines 39-50). In regards to claim 25, the claim is drawn to "a composition consisting essentially of..." In regards to claim 27, the claim is drawn to "a kit comprising: a first composition consisting essentially of..." Applicant has not defined what encompasses "consisting essentially of" in the specification. In fact the instant specification does not define the phrase "consisting essentially of". The MPEP states the following: "The transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. A 'consisting essentially of' claim occupies the middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format...For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to 'comprising'" (see MPEP 2105). Therefore, claims 25 and 28 have been treated as "a composition comprising…" the same claim language as original claim 3.

The difference between the reference and the instant claims is that the reference does not teach a kit or an anti-cancer drug.

21. However, Salvati et al teach a fused cyclic compound and the use of the fused cyclic compound with a nutritional supplements in combination with whey protein or casein, amino acids (such as leucine, branched amino acid and hydroxymethylbutyrate), triglycerides, vitamins (e.g., A, B6, B12, folate, C, D, and E), minerals, etc (see column 45, lines 48-56). Furthermore, the reference teaches anti-proliferative agents for use in combination with the compounds such as adriamycin (see column 45, lines 41-43) and anti-cancer agents, such as methotrexate, 5-fluorouracil (see column 46, lines 64-67). The reference teaches a kit comprising a first container (such as a vial) containing a pharmaceutical formulation comprising a compound, a second container (such as a vial) containing a pharmaceutical formulation comprising one or more agents to be used in combination with the compound of the invention (see 47, lines 55-64).

22. Therefore, it would have been obvious for one of ordinary skill in the art to combine the teachings of Hageman et al and Salvati et al to produce a kit comprising the anti-cancer agent with the nutritional composition, since Salvati et al teach a kit comprising fused cyclic compound, nutritional supplement comprising leucine, whey and protein and any anti-cancer agent and Hageman et al teach the nutritional composition. One of ordinary skill in the art would be motivated to combine, since Salvati et al teaches such a composition/kit. Furthermore, one of ordinary skill in the art would have been motivated to optimize the concentrations of the essential amino acids, since “it is

the normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is optimum combination of percentages". The MPEP states: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. *"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."* In re Aller, *220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)* (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("*The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.*"); In re Hoeschele, *406 F.2d 1403, 160 USPQ 809 (CCPA 1969)* (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990);

and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Therefore, there is a reasonable expectation of success to optimize the concentrations of the essential amino acid, since it is "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages" and one of ordinary skill in the art would experiment with different concentrations to produce the optimal product. From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary. There is a reasonable expectation of success, since Salvati et al teach a kit that can comprise any agent, nutritional supplement for the treatment of cancer (prostate), and Hageman et al teach a nutritional supplement that is useful in treating variety of diseases, including cancer.

Response to Applicant's Arguments

23. Applicant argues "the presently claimed invention, as set forth in amended independent claims 3 and 25, as well as dependent claims 4, 7 and 27, are drawn to compositions that provide (1) leucine, either in free and/or salt form, at a concentration of at least about 25%, and (2) a ratio of total essential amino acids, and optionally, conditionally essential amino acids to total amino acids that ranges from about 0.60 to about 0.90." Applicant further argues that "Salvati fails to disclose and suggest the

claimed kits wherein the level of leucine is at least about 25% and the ratio of total essential amino acids and, optionally, conditionally essential amino acids, to total amino acids that ranges from about 0.60 to about 0.90."

24. Applicant's arguments have been fully considered but have not been found persuasive. Hageman patent teaches that in supplements for sportsmen and persons that temporarily require high protein requirements, up to 60 g of protein per daily dose can be included (see column 6, lines 48-53). Since the reference teaches that when relative large amounts of proteins or amino acids are included in the product, it is preferred to increase the amount of vitamin B6 in the product (see column 7, lines 3-5). Therefore, it would have been obvious to one of ordinary skill in the art to optimize the concentrations of the essential amino acids to achieve the optimal nutritional composition. Essential amino acids added together (isoleucine, leucine, lysine, methionine, phenylalanine and threonine) would add up to 0.80, which is within the range of 0.60 and 0.90. For example, 10% Ile, 10% Leu, 15% Lys, 15% Met, 15% Phe, and 15% Thr, added would lead to 0.80. Furthermore, one of ordinary skill in the art would have been motivated to optimize the concentration of essential amino acids in the nutritional composition, since "it is the normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is optimum combination of percentages". Salvati reference teaches a nutritional supplement and a kit comprising a first container (such as a vial) containing a pharmaceutical formulation comprising a compound, a second container (such as a vial) containing a pharmaceutical formulation comprising one or

more agents to be used in combination with the compound of the invention (see 47, lines 55-64). From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary. There is a reasonable expectation of success, since Salvati et al teach a kit that can comprise any agent, nutritional supplement for the treatment of cancer (prostate), and Hageman et al teach a nutritional supplement that is useful in treating variety of diseases, including cancer.

New Objection

25. Page 4 of the claim is objected to for the following minor informality: There appears to be an error in between claims 15-16. Claim 15 has been cancelled. However, right above claim 16, there is a "0". Applicant is requested to correct the error.

New Rejection

35 U.S.C. 112, 2nd

26. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

27. Claims 3, 16 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

28. Claims 3 and 25 recite, "…wherein said leucine, in free and/or salt form, is present in an amount of at least about 25%, and…the ratio of the intact protein to leucine, in free form and/or salt form, ranges from about 10:1 to about 1:10." It is unclear how having at least 25% of leucine would lead to a ratio of the intact protein to leucine ranging from about 10:1 to about 1:10.

29. Claim 16 recites, "The composition of claim 3, comprising from about 36 g to about 72 g total essential and/or conditionally essential amino acids per serving." Claim 16 is dependent on claim 3, and claim 3 recites, "said composition provides a ratio of total essential amino acids and, optionally, conditionally essential amino acids to total amino acids ranging from about 0.60 to about 0.90…" It is unclear how about 36 g to about 59g of total essential and/or conditionally essential amino acids per serving would give a ratio ranging from about 0.60 to about 0.90.

Conclusion

30. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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